Pre-Procedure Review Process

This process is required for a site's first 5 implants. This applies to Roll-In and Randomized subjects (CLAAS® or Control). Sites who previously met these criteria are not required to complete this process prior to enrolling subjects into the CONFORM Pivotal Trial. For all subjects at all sites, screening imaging must be uploaded to Medidata Intelemage and reviewed by Conformal prior to randomizing a subject or confirming a roll-in case.

The purpose of this Pre-Procedure Review Process is to review the subject candidate's LAA anatomy suitability prior to roll-in or randomization.

Once the subject has consented, Implanters will present their site's first subject candidate TEE or CT images to at least one member of the Executive Committee or designee(s), the "Committee." The remaining four pre-procedure review subjects do not require a live presentation.

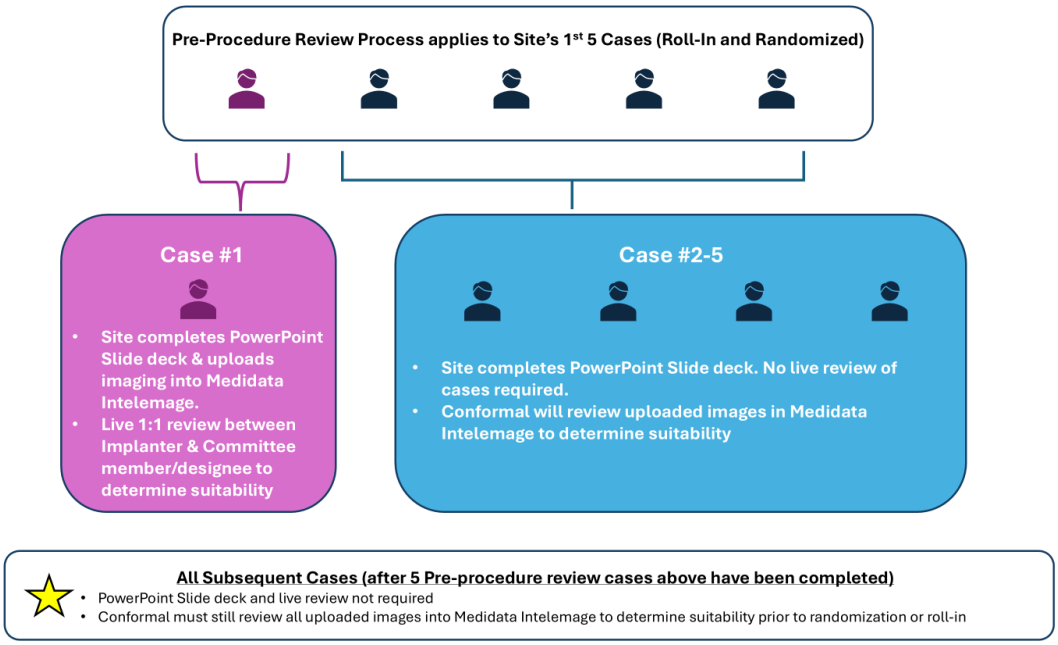

Figure 1 Pre-Procedure Review Process: First Case

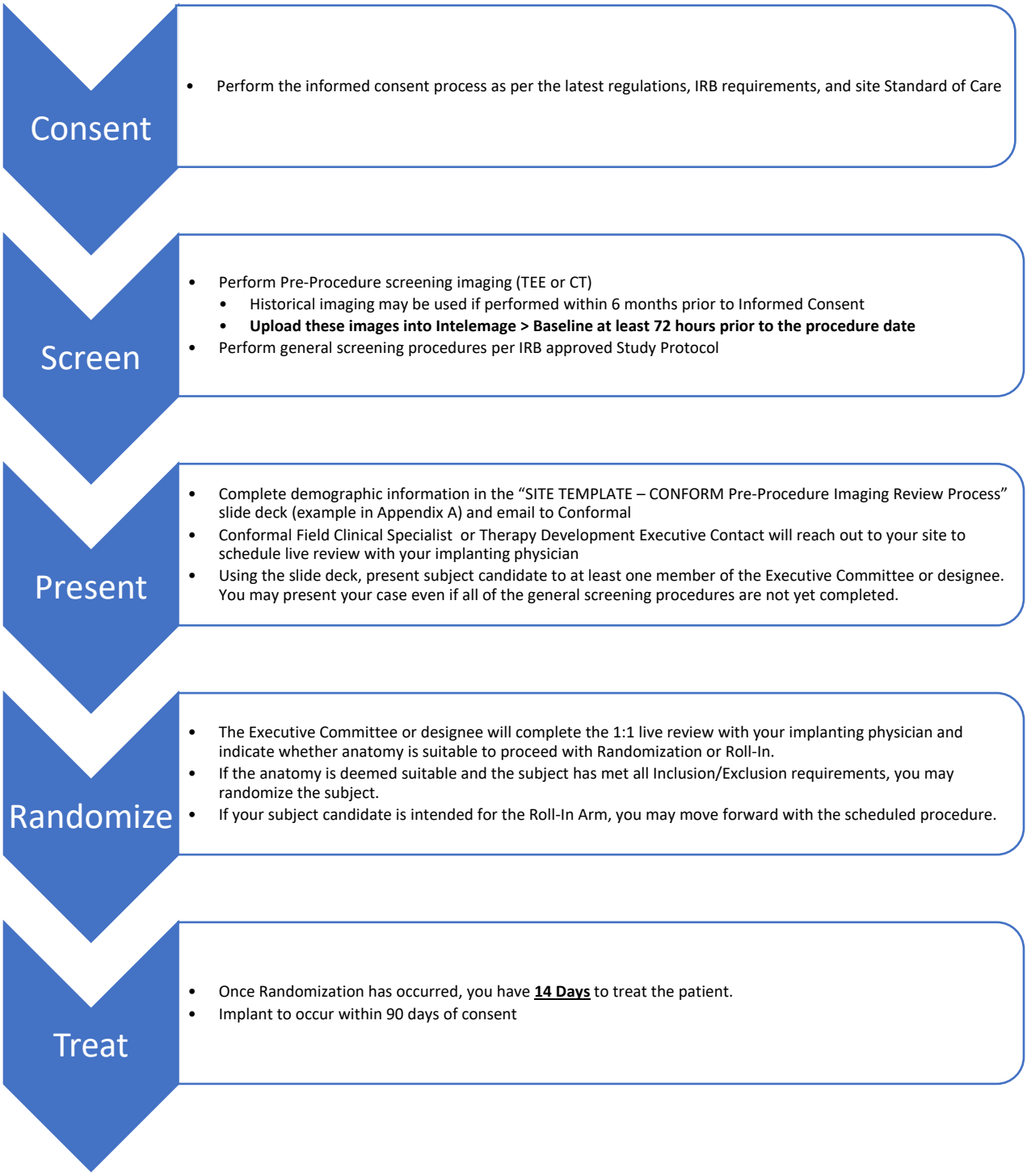

Figure 2 Pre-Procedure Review Process: Remaining Four Cases

Consent

- Perform the informed consent process as per the latest regulations, IRB requirements, and site Standard of Care

Screen

- Perform Pre-Procedure screening imaging (TEE or CT)
  - Historical imaging may be used if performed within 6 months prior to Informed Consent
  - **Upload these images into Intelemage > Baseline at least 72 hours prior to the procedure date**
- Perform general screening procedures per IRB approved Study Protocol

Complete Slide Deck

- Complete demographic information in the "SITE TEMPLATE – CONFORM Pre-Procedure Imaging Review Process" slide deck (example in Appendix A) and email to Conformal

Randomize

- The Conformal Imaging Manager or FCS designee will review the images to determine if the anatomy is appropriate for the CONFORM Trial. If the anatomy is deemed suitable and the subject has met all Inclusion/Exclusion requirements, you may randomize the subject.
- **Do not randomize the subject in Medidata until you have received notification from Conformal of anatomical suitability.**
- If your subject candidate is intended for the Roll-In Arm, you may move forward with the scheduled procedure.

Treat

- Once Randomization has occurred, you have **14 Days** to treat the patient.
- Implant to occur within 90 days of consent

Frequently Asked Questions

Q: Does the requirement to screen the first 5 cases apply to the site or to each operator? What if my site has more than one procedure location?
A: This process is intended to apply per site, even if your site has more than one procedure location. Study Management may adjust based on specific practices at the site.

Q: When do I initiate the Pre-Procedure Review Process?
A: Once a subject has signed the consent form, we recommend you initiate the Pre-Procedure Review Process as soon as feasibly possible. If not already in receipt, contact your Site Manager and they will forward you the Slide Deck template. For the first case, a Conformal Field Clinical Specialist or Therapy Development Executive Contact will reach out to your site to schedule the live review with the implanting physician. Reminder: Initiating this process 10-14 days before the scheduled procedure is recommended.

Q: What do I need to do to prepare for the Pre-Procedure Review?
A: Using the Sponsor-generated PowerPoint template (example in Appendix A), you will provide general background information for each subject candidate planned for Pre-Procedure review. Ensure that you have uploaded required baseline imaging into Medidata Intelemage, as a Conformal Field Clinical Specialist or Imaging Manager will embed these TEE or CT images into the PowerPoint template.

Q: When does the Pre-Procedure Imaging Review occur?
A: If you have historical TEE or CT images on file and uploaded into Medidata Intelemage, we can schedule it as soon as the implanter is available. If you still have to conduct a Screening TEE or CT, we will wait to complete the Pre-Procedure Imaging Review until after imaging is available and uploaded into Intelemage.

Q: Can I use a historical TEE or CT Image within 6 months of consent?
A: Yes.

Q: If performed after consent, will TEE or CT Images count towards subject screening images/eligibility?
A: Yes. These images can be used to assess the subject Echo Exclusion Criteria.

Q: How do I schedule the live Pre-Procedure Review and how long does that review take?
A: Communicate your screening/imaging plans with your Site Manager as soon as your subject is consented, and a possible implant date has been determined. Your Site Manager, Executive Contact, and/or a Conformal Field Clinical Specialist will work with you to schedule a time for the 1:1 live Pre-Procedure Imaging Review. The call will likely take 15 minutes or less.

Q: Who from the Site will present the Subject Candidate to the Committee member or designee?
A: The Implanter will present the Subject Candidate to the Committee member or designee. Any site personnel who may benefit from joining the discussion can attend.

Q: What format will the presentation be in?
A: The presentation will be via video conference, which Conformal Medical will set up, with video conference link.

Q: How do I obtain the Sponsor generated PowerPoint template?
A: Your Site Manager will provide the Sponsor generated PowerPoint template that the Implanter will use to present to the Committee.

Q: What am I expected to fill in the Sponsor generated PowerPoint template?
A: The PowerPoint template highlights the sections for your site to fill. This includes Pages 2 –4. You will need to provide basic information about the case to be presented such as procedural team, subject demographics and brief medical history.

Q: Do I need to upload these images to Intelemage?
A: Yes, you will upload the TEE or CT images used for screening in Intelemage. Navigate to the Baseline Visit timepoint to upload your images.

Q: Our site has already performed 5 cases; do we need to follow this process?
A: No, once the site has completed 5 cases, whether Roll-In or Randomized, you do not need to follow this process. However, all subsequent CONFORM cases must have image review performed by the FCS team at least 72 hours prior to the procedure to evaluate anatomy. No slide deck is required following the first 5 cases.

Q: After our site's first 5 cases, do we still have to wait for Conformal to review baseline imaging prior to randomization?
A: Yes, *for all subjects,* wait for the notification from Conformal of anatomical suitability before randomizing the subject in Medidata.

Appendix A Follows
SITE TEMPLATE - CONFORM Pre-Procedure Imaging Review Process Example V5.0 05MAR2025